REMARKS

Claims 5-9 were objected to under 37 CFR 1.75(c) and not treated on the merits by reason of improper form due to multiple dependencies. However the multiple dependencies of Claims 4-6 were eliminated in the Preliminary Amendment submitted at the time of national stage entry of this application. Claims 7-9 have never been multiply dependent.

Claims 1-4 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. 6,980,112 (Nee). Amended Claim 1 describes a device arranged for carrying out a bioelectrical interaction with an individual through electrodes and detecting undesired contact of an electrode with the individual, said device comprising a plurality of electrodes arranged to receive a physiological electrical signal when brought into contact with an individual's skin; testing means arranged to deliver a second electrical signal to an input of the electrodes, said electrodes being further arranged to generate a response signal upon receipt of the second electrical signal; control unit arranged to analyze the first electrical signal and to actuate the testing means upon an occurrence of a predetermined event in the first electrical signal; and lead-off detection means arranged to verify an integrity of the contact of said electrodes by analyzing the response signal and detecting a parameter related to said integrity. In principle, there are two approaches for detecting a loose electrode which is to receive a physiological electrical signal through its contact with the body of a patient: passive techniques and active techniques. Passive techniques involve analyzing the received physiological signals and trying to detect an effect of a loose electrode from the signal characteristics. However bodily electrical signals are of very low intensity, causing this approach to be difficult and often ambiguous. An active approach is taken with many ECG monitoring systems. The

typical active approach is to inject a small signal into a reference electrode, usually the "right leg drive" (RLD) electrode. The injected signal is received by the other electrodes of the electrode set and, when the electrodes are properly attached to the body, will be received uniformly by the other electrodes. A comparison of the electrode signals of two or more electrodes will result in no appreciable result from the injected signal as the signal will manifest itself as a common mode signal at all of the electrodes. But if an electrode is loose, the injected signal will not appear strongly or at all at that electrode, and comparison with a signal from another correctly attached electrode will cause the injected signal to appear as it will no longer be a common mode phenomenon. This active approach is unambiguous in comparison with most passive techniques.

The present invention describes a device and method which is passive and selectively active. The physiological signal is monitored for an abnormal condition or event such as low amplitude or high noise content. If such an event is sensed, raising suspicion of a loose electrode, a test signal is generated and applied to an input of an electrode. The response to the test signal is analyzed to confirm or deny the existence of a loose electrode. An advantage of this approach is that a dedicated RLD-type electrode is not needed. Since the test signal is applied selectively, it can be applied to a physiological signal sensing electrode. While this may disrupt reception of the physiological signal momentarily, this is acceptable because the disruption only occurs briefly when a loose electrode condition is suspected by the control unit. The typical RLD approach applies the injected signal continuously, thus the need for a dedicated electrode.

The Nee patent describes an implanted therapeutic device such as a pacemaker or implanted defibrillator. An intracardiac electrogram (IEGM) is constantly taken by an implanted lead and analyzed for an emergency cardiac condition

such as ventricular tachycardia or fibrillation. If an emergency condition is detected a distress signal is sent to an external system where a decision is made whether to delivery therapy such as a defibrillating shock. There is no sensing of loose leads or electrode contact in Nee. There is no testing means delivering a second electrical signal to an electrode when the analysis of the physiological signal from the electrode indicates an event has occurred in the physiological signal and no lead-off detector which verifies the integrity of the electrode contact from the response to the second signal. In Nee an IEGM is constantly acquired and analyzed and when the analysis indicates a need for therapy a therapeutic pulse, either a high energy defibrillating shock or low energy cardioversion shock, is delivered to the heart. The integrity of electrode contact is not of concern to Nee since the IED and its leads are implanted in the body. It is therefore respectfully submitted that Nee does not render Claim 1 and its dependent Claims 2-6 unpatentable.

Claim 7 describes a method for on-demand verification of the integrity of electrical contact of an electrode to a body part. The method comprises measuring a first physiological electrical signal by means of the electrode; analyzing the first physiological electrical signal for occurrence of a predetermined event; generating a second electrical signal upon detection of the predetermined event; generating a response signal by applying the second electrical signal to an input of the electrode; and analyzing the response signal for detecting a parameter related to said integrity. Similar to Claim 1, the method has a passive phase of measuring and analyzing a physiological signal for occurrence of an event indicative of poor electrode contact. If such an event occurs, it triggers the generation of a signal which is applied to an electrode, the active phase of the method. The response to the second signal is analyzed for a parameter related to the integrity of the electrode contact. As

previously discussed, Nee is unconcerned with electrode contact integrity. Nee does not monitor a physiological signal for an indication of an integrity problem, nor does he respond to such an indication by applying a signal to an electrode to produce a response that indicates the integrity of electrode contact. For these reasons it is respectfully submitted that Claim 7 and its dependent Claims 8 and 9 are patentable over Nee.

The prior art made of record and not relied upon has been reviewed and is not believed to affect the patentability of Claims 1-9 as amended above. Like, Nee, none of these other patents seem concerned with loose electrode detection.

In view of the foregoing amendment and remarks it is respectfully submitted that Claims 1-9 are patentable over Nee. It is therefore respectfully requested that the rejection of Claims 1-4 under 35 U.S.C. §103(a) be withdrawn, and that Claims 5-9 be allowed.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

HARALD REITER ET AL.

By: /W. Brinton Yorks, Jr./
W. Brinton Yorks, Jr.
Reg. No. 28,923

Philips Electronics
22100 Bothell Everett Highway
P.O. Box 3003
Bothell, WA 98041-3003
(425) 487-7152
February 7, 2008